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EXAMINER

TABATABAI, ABOLFAZL

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,731	<b>Applicant(s)</b> TSOUGARAKIS ET AL.	
	<b>Examiner</b> ABOLFAZL TABATABAI	<b>Art Unit</b> 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,11-19,21,25,26,29,33,38,39 and 41-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,11-19,21,25,26,29,33,38,39 and 41-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/4/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**Response to Amendments/Arguments**

1. Applicant's arguments, see (pages 12-22), filed on February 4, 2008, with respect to the rejection(s) of claims 1, 3-6, 18, 22, 24-26 and 29 under Webber (U. S. 6,081,577); claims 2 and 19 under Webber (U. S. 6,081,577) and Thesen et al (U. S. 6,556,855 B2); claims 11-17, 21 and 33 under Webber (U. S. 6,081,577) and Aylward et al (U. S. 6,690,816 B2); claim 38 under Webber (U. S. 6,081,577) and Bonutti (U. S. 6,702,821 B2); and claims 39 and 41 under Webber (U. S. 6,081,577) and Bonutti (U. S. 6,702,821 B2) in view of Thesen et al (U. S. 6,556,855 B2); have been fully considered and persuasive. Therefore, upon further consideration, a new ground(s) of rejection is made in view of Webber (U. S. 6,081,577); Guo et al (U. S. 6,155,521); Thesen et al (U. S. 6,556,855 B2) and Valentine (U. S. 5,759,205).

**Claim Rejections - 35 USC § 103**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-6, 9, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber (U. S. 6,081,577) in view of Guo et al (U. S. 6, 15, 521).

Regarding claim 1, Webber discloses a method comprising:

obtaining a first image(s) of a body part in a first plane (column 20, lines 22-31), wherein the first image(s) generates a first image data volume (column 4, lines 40-47 and column 21, lines 15-57);

obtaining a second image(s) of the body part in a second plane (column 20, lines 22-31), wherein the second image(s) generates a second image data volume (column 4, lines 40-47 and column 21, lines 15-57).

However, Webber is silent about the specific details regarding the steps of:

extracting boundary image data from each of the first and second image data volumes; and combining the extracted boundary image data to form a resultant boundary data volume.

In the same field of endeavor (medical imaging), however, Guo discloses medical support system comprising the steps of:

extracting boundary image data from each of the first and second image data volumes (please note, to column 4, lines 17-28 and column 13, lines 34-46); and combining the extracted boundary image data to form a resultant boundary data volume (please note, to column 13, lines 34-46).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use combining the extracted boundary images as taught by Guo in the system of Webber because Guo provides Webber an improved system capable of providing a medical treater with images wide in vidual field and high in resolution.

Regarding claim 3, Webber discloses the method according to claim 1, wherein the second image(s) is taken at an angle between about 0 and about 180 degrees from the first image(s) (column 25, lines 55-62).

Regarding claim 4, Webber discloses the method of claim 1, wherein the first image(s) is taken at a first angle and the second image(s) is taken at a second angle, and further wherein the first angle does not equal the second angle (column 4, lines 20-31).

Regarding claim 5, Webber discloses the method of claim 1, wherein the first image(s) is taken at a first time and the second image(s) is taken at a second time (column 3, lines 22-27).

Regarding claim 6, Webber discloses the method of claim 3, wherein the second image(s) is taken at an angle between about 0 and about 90 degrees from the first image. (column 27, lines 19-20).

Regarding claim 9, Webber discloses the method of claim 1, further including: obtaining at least one additional image of a body part in a plane different than other planes, wherein the additional image generates an additional image data volume (column 4, lines 17-31).

However, Webber is silent about the specific details regarding wherein boundary image data is extracted from the additional data volume; and wherein the boundary image data from the additional data volume is combined with the boundary image data from first and second image data volumes to form a resultant boundary data volume.

In the same field of endeavor (medical imaging), however, Guo discloses medical support system comprises wherein boundary image data is extracted from the additional data volume (please note, to column 4, lines 17-28); and wherein the boundary image data from the additional data volume is combined with the boundary image data from first and second image data volumes to form a resultant boundary data volume (please note, to column 4, lines 17-28 and column 13, lines 34-46).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use combining the extracted boundary images as taught by Guo in the system of Webber because Guo provides Webber an improved system capable of providing a medical treater with images wide in vidual field and high in resolution.

Claim 44 is similarly analyzed as claim 6 above.

Claim 47 is similarly analyzed as claim 1 above.

**5.** Claims 11-18, 21, 25, 26, 29, 33, 38, 41, 42, 45, 46, 52-58, 63, 65, and 67-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber (U. S. 6,081,577) in view of Hollister et al (U. S. 7,174,282 B2).

Regarding claim 11, Webber discloses a method for designing an implant for a body part, comprising:

obtaining a first image data volume from a first image(s) in a first plane (column 20, lines 22-31);

obtaining a second image data volume from a second image(s) in a second plane (please note, to column 20, lines 22-31);

combining image data to form each of the first and second image data volumes (please note, to column 4, lines 54-58 and column 19, lines 63-67).

However, Webber is silent about the specific details regarding the step of:

using the combined image data to derive an implant shape.

In the same field of endeavor (medical imaging), however, Hollister discloses design methodology tissue engineering scaffolds and biomaterial implant comprising the step of:

using the combined image data to derive an implant shape (please note, to abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the combined image data to derive an implant shape as taught by Hollister in the system of Webber because Hollister provides Webber an improved method which is useful for orthopedic and cranial facial device industries, tissue engineering industries, and drug delivery system and pharmaceutical industries.

Claim 12 is similarly analyzed as claim 11 above.

Regarding claim 13, Webber discloses the method of claim 11, wherein the resultant image data volume is near isotropic (please note, to column 19, lines 63-67).

Regarding claim 14, Webber discloses the method of claim 11, wherein the resultant image data volume is isotropic (please note, to column 6, lines 65-67).

Claim 15 is similarly analyzed as claim 4 above.

Regarding claim 16, Webber discloses the method of claim 15, wherein the angle between about 0 and about 180 degrees (please note to column 25, lines 55-62).

Regarding claim 17, Webber discloses the method of claim 16, wherein the angle between about 0 and about 90 degrees (please note, to column 27, lines 19-20).

Regarding claim 18, Webber discloses a method for treating a body part, comprising:

acquiring at least two data volumes from at least two body part images performed in two different planes (please note, to column 4, lines 40-47 and column 21, lines 15-57); combining the data volumes to form a resultant data volume (please note, to column 4, lines 17-31).

However, Webber is silent about the specific details regarding the step of:

deriving a therapy for the body part using the resultant data volume.

In the same field of endeavor (medical imaging), however, Hollister discloses design methodology tissue engineering scaffolds and biomaterial implant comprising the step of:

deriving a therapy for the body part using the resultant data volume (please note, to column 1, lines 13-17 and column 12, line 11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a therapy for the body part as taught by Hollister in the



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system of Webber because Hollister provides Webber an improved method which is useful for orthopedic and cranial facial device industries, tissue engineering industries, and drug delivery system and pharmaceutical industries.

Claim 21 is similarly analyzed as claim 6 above.

Regarding claim 25, Webber discloses a method comprising:

obtaining at least one image of a body part in at least a first plane and a second plane, wherein the first plane generates a first image data volume and the second plane generates a second image data volume (please note, to column 4, lines 40-47 and column 21, lines 15-57); combining the first and second image data volumes to form a resultant image data volume (please note, to column 4, lines 17-31), wherein the resultant image data volume is near-isotropic or isotropic (please note, to column 19, lines 63-67).

However, Webber is silent about the specific details regarding the step of:

using the resultant image data volume to derive an implant shape.

In the same field of endeavor (medical imaging), however, Hollister discloses design methodology tissue engineering scaffolds and biomaterial implant comprising the step of:

using the resultant image data volume to derive an implant shape (please note, to abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the combined image data to derive an implant shape as taught by Hollister in the system of Webber because Hollister provides Webber an

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improved method which is useful for orthopedic and cranial facial device industries, tissue engineering industries, and drug delivery system and pharmaceutical industries.

Claim 26 is similarly analyzed as claims 1 and 11 above.

Claims 29 and 41 are similarly analyzed as claim 6 above.

Claims 33 and 47 are similarly analyzed as claim 5 above.

Claims 52, 67 and 72 are similarly analyzed as claim 11 above.

Claims 53, 68 and 73 are similarly analyzed as claim 12 above.

Claim 54 is similarly analyzed as claim 13 above.

Claim 55 is similarly analyzed as claim 14 above.

Claims 56, 69 and 74 are similarly analyzed as claim 15 above.

Claims 57, 70 and 75 are similarly analyzed as claim 16 above.

Claims 58, 65, 71 and 76 are similarly analyzed as claim 17 above.

Claims 42, 45, 46 and 63 are similarly analyzed as claim 26 above.

Regarding claim 38, webber discloses a method for designing an implant for a body part, comprising:

acquiring at least two data volumes from at least two body part images performed in two different planes (please note, to column 20, lines 22-31);

combining the data volumes to form a resultant data volume (column 4, lines 24-31).

However, Webber is silent about the specific details regarding the steps of:

deriving the three-dimensional shape of the body part from the resultant data volume; and deriving an implant shape utilizing the three- dimensional shape information.

(column 51, lines 31-36).

In the same field of endeavor (medical imaging), however, Hollister discloses design methodology tissue engineering scaffolds and biomaterial implant comprising the steps of:

deriving the three-dimensional shape of the body part from the resultant data volume (please note, to abstract); and deriving an implant shape utilizing the three-dimensional shape information (please note, to abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use deriving an implant shape utilizing the three- dimensional shape information as taught by Hollister in the system of Webber because Hollister provides Webber an improved method which is useful for orthopedic and cranial facial device industries, tissue engineering industries, and drug delivery system and pharmaceutical industries.

**6.** Claims 19, 39 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber (U. S. 6,081,577) and Guo et al (U. S. 6, 15, 521) as applied to claims 1, 38, 63 and further in view of Thesen et al (U. S. 6,556,855 B2).

Regarding claim 19, Webber and Hollister are silent about the specific details regarding the method according to claim 18, wherein the combining step comprises:

obtaining gray values for each data point in each of the data volumes;

interpolating a resultant gray value from gray values; and,  
assigning said resultant value to each data point of the resultant data volume.  
In the same field of endeavor (medical imaging), however, Thesen discloses method for implementation of a perfusion measurement with magnetic resonance imaging comprising the steps of:

obtaining gray values for each data point in each of the data volumes (please note, to column 6, lines 24-31); interpolating (please note, to column 4, lines 54-58) a resultant gray value from gray values (please note, to column 6, lines 24-31); and,  
assigning said resultant value to each data point of the resultant data volume (please note, to column 6, lines 9-16).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use gray values and interpolation as taught by Thesen in the system of Webber because Thesen provides Webber an improved method for the implementation of a perfusion measurement with MRI that, among other things avoids the aforementioned disadvantageous of known perfusion measurements.

Claims 39 and 64 are similarly analyzed as claim 19 above.

**7.** Claims 43 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber (U. S. 6,081,577) and Guo et al (U. S. 6, 15, 521) as applied to claim 1 above and further in view of in view of Valentine (U. S. 5,759,205).

Regarding claim 43, Webber and Hollister are silent about the specific details regarding the method of claim 42, wherein the implant is selected from the group consisting of knee, hip, spine and shoulder implants.

In the same field of endeavor (medical imaging), however, Valentine discloses negatively charged polymeric electret implant comprises the implant is selected from the group consisting of knee, hip, spine and shoulder implants (please note, to column 8, lines 18-21).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use hip implant, spine implant, knee implant and shoulder implant as taught by Valentini in the system of Webber because Valentini provides Webber a biocompatible implant having improved host tissue compatibility and ingrowths capability.

Claim 66 is similarly analyzed as claim 43 above.

8. Claim 48-51 and 59-62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webber (U. S. 6,081,577) and Guo et al (U. S. 6, 15, 521) as applied to claims 11 and 52 above and further in view of Valentine (U. S. 5,759,205).

Regarding claim 48, Webber and Hollister are silent about the specific details regarding the method of claim 11, wherein the implant is a knee implant.

In the same field of endeavor (medical imaging), however, Valentine discloses negatively charged polymeric electret implant comprises the implant is a knee implant (please note, to column 8, lines 18-21).

Regarding claim 49, Webber and Hollister are silent about the specific details regarding the method of claim 11, wherein the implant is a hip implant.

In the same field of endeavor (medical imaging), however, Valentine discloses negatively charged polymeric electret implant comprises the implant is a hip implant (please note, to column 8, lines 5-7).

Regarding claim 50, Webber and Hollister are silent about the specific details regarding the method of claim 11, wherein the implant is a spine implant.

In the same field of endeavor (medical imaging), however, Valentine discloses negatively charged polymeric electret implant comprises the implant is a spine implant (please note, to column 8, lines 21-27).

Regarding claim 51, Webber and Hollister are silent about the specific details regarding the method of claim 11, wherein the implant is a shoulder implant combined image data to select an implant shape.

In the same field of endeavor (medical imaging), however, Valentine discloses negatively charged polymeric electret implant comprises the implant is a shoulder implant (please note, to column 8, lines 18-21).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use hip implant, spine implant, knee implant and shoulder implant as taught by Valentini in the system of Webber because Valentini provides Webber a biocompatible implant having improved host tissue compatibility and ingrowths capability.

Claim 59 is similarly analyzed as claim 48 above.

Claim 60 is similarly analyzed as claim 49 above.

Claim 61 is similarly analyzed as claim 50 above.

Claim 62 is similarly analyzed as claim 51 above.

### **Contact Information**

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ABOLFAZL TABATABAI whose telephone number is (571) 272-7458.

The Examiner can normally be reached on Monday through Friday from 9:30 a.m. to 7:30 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bhavesh Mehta, can be reached at (571) 272-7453. The fax phone number for organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Abolfazl Tabatabai/

Primary Examiner, Art Unit 2624

April 7, 2008